Standalone Clinical Decision Support (CDS)

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What is CDS?

- Uses an individual's information from various sources (electronically or manually entered)

- Converts this information into new information that is intended to support a clinical decision

- Could be a mobile application, web-based service or desk top application

Definition of device

SEC. 201. [321] For the purposes of FD&C Act –

(h) The term "device" … means an instrument, apparatus, implement, machine, **<u>contrivance</u>**, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is

   (1)   recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) <u>**intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals**</u>, or

   (3)   intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

Information sources

How information gets to CDS is not relevant to definition

Information might be

- entered by a person
- transferred electronically from a manually connected device
- collected and entered by a connecting device
- environmental data (pollen count, temperature, etc)
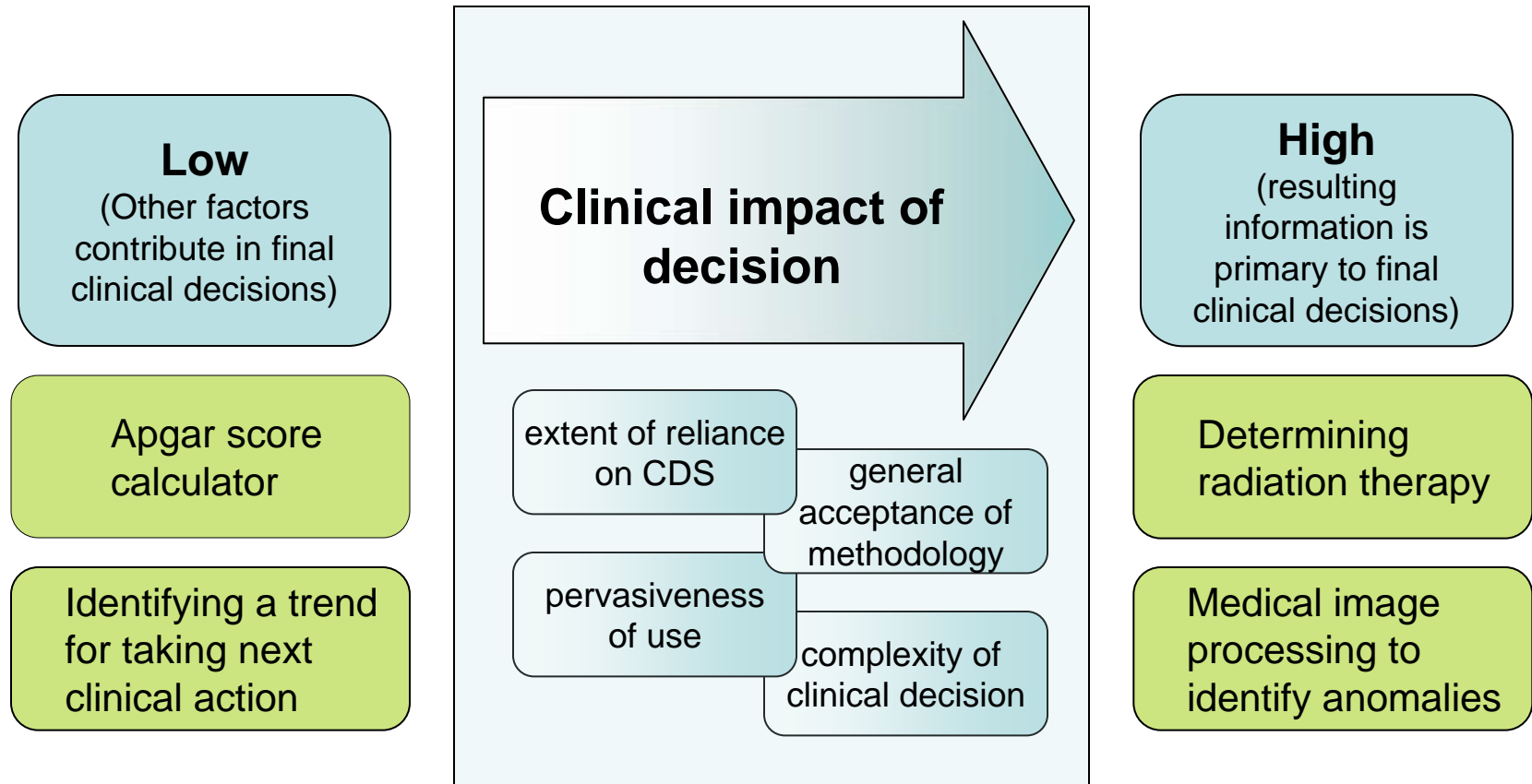- demographic data

Information conversion

How information is converted to new information that helps in making clinical decision is important

Converting or analyzing could include

- using algorithms (fixed or iterative)
- using formulae
- database look-ups or comparisons
- using rules and associations

CDS landscape

Low
(Other factors contribute in final clinical decisions)

Apgar score calculator

Identifying a trend for taking next clinical action

Clinical impact of decision

extent of reliance on CDS

general acceptance of methodology

pervasiveness of use

complexity of clinical decision

High
(resulting information is primary to final clinical decisions)

Determining radiation therapy

Medical image processing to identify anomalies

U.S. Food and Drug Administration
Protecting and Promoting Public Health

Examples of CDS

- calculates creatinine clearance or BMI
- gives reminders for tests, consults or medications
- checks for drug-drug interaction
- checks for allergies

- directs where to biopsy
- suggests cancer treatment based on proprietary algorithm, not widely accepted
- provides radiation treatment recommendation from combines multiple physio-logical inputs
- interprets complex information to an untrained user

Premarket assessment includes …

Safety

- There is reasonable assurance … that the probable benefits … outweigh any probable risks   [21CFR860.7(d)(1)]

Effectiveness

- There is reasonable assurance that … the use of the device … will provide clinically significant results   [21CFR860.7(e)(1)]

Factors to consider

- Level of *impact* on subject health condition/disease

- Degree of *acceptance* in clinical practice

- Ability to easily *identify erroneous output*
  - procedurally errors (due to incorrect input or software flaws)
  - clinically wrong information